

REMARKS

I. Status of the Claims

With this submission, claim 28 and 29 are newly added. No claims have been amended or canceled. Hence, upon entry of this paper, claims 24-29 will be under examination.

Support for newly added claims 28 and 29 can be found throughout the specification. Specifically, support can be found on page 26 lines 11-14 of the original specification.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

II. Withdrawn Rejections

Applicants wish to thank the Examiner for withdrawing the rejections to claim 24 and 25 based on 35 U.S.C. §102(e) by Rinella. Additionally, applicants wish to thank the Examiner for withdrawing the rejections to claim 24 and 25 based on 35 U.S.C. §102(a) by Hayashi.

III. Obviousness-Type Double Patenting

Claims 24 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-12 of U.S. Pat. No. 7,291,594 (“the ’594 patent”). (Office Action, at page 3 paragraph 7.)

The Examiner correctly acknowledges that “the conflicting claims are not identical.” (Office Action, page 3, paragraph 7). Additionally, claims 24 and 25 are not obvious over the ’594 patent because the GLP-1 peptide is selected from GLP-1(7-35). In contrast, the claimed invention is selected from a larger peptide. Therefore, claims 24 and 25 are not obvious over claims 1-12 of the ’594 patent.

IV. Claim Rejections Under 35 U.S.C. § 103- Rinella in view of Hayashi

Claims 24 and 25 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Rinella, U.S. Pat. No. 6,440,930 (“Rinella”) in view of Hayashi, (JP 2002-299283). (Office Action, at page 4 paragraph 12.)

A. Hayashi does not qualify as prior art

WO 2004/037859 (corresponding to JP2002-299283) was first published on May 6, 2004. Applicants' application (US 10/550,624), however, has a priority date of March 28, 2003. Accordingly, WO2004/037859 cannot be used as prior art against the instant application. JP 2002-299283 was withdrawn on January 11, 2004, and thus not published before May 6, 2004. Therefore, Hayashi JP 2002-299283 is also not prior art against this application.

B. Rinella Does Not Teach Each and Every Element

And even if Hayashi qualifies as prior art, the deficiency in the teachings of Hayashi are not made up for in Rinella.

When determining whether a claim is obvious, an examiner must make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, "*there must be some articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)). The failure of an asserted combination to teach or suggest each and every feature of a claim remains fatal to an obviousness rejection under 35 U.S.C. § 103 and MPEP 2143.03.

Rinella does not teach the trypsin-resistance of GLP-1 derivatives. Rinella discloses many substitutions of the amino acids in GLP-1 derivatives. One of skill in the art looking to Rinella would not know how to make GLP-1 derivatives trypsin-resistant by substituting amino acids in accordance with the disclosure of Rinella. Applicants were the first to discover derivatives of GLP-1 that are trypsin resistant. Specifically, inventors were the first to discover that the combination of substitutions of lysine (Lys) to glutamine (Gln) at the 26th position and the substitution from lysine (Lys) to asparagines (Asn) at the 34th position in GLP-1 derivatives give the GLP-1 derivatives trypsin-resistance.

For at least these reasons, Applicants thus respectfully request withdrawal of the rejections based on 35 U.S.C. §103.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request that the Examiner reconsider all rejections and that they be withdrawn. Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

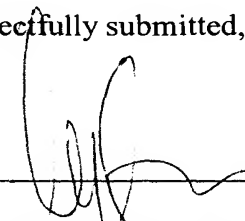
Respectfully submitted,

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